

SUB C1 (9) the nanoparticulate drug particles comprise a poorly soluble drug, have an effective average particle size of less than about 1000 nm, and have a surface modifier adsorbed on the surface of the drug.

52. The aerosol composition of claim 51, wherein the drug is selected from the group consisting of proteins, peptides, bronchodilators, corticosteroids, elastase inhibitors, analgesics, anti-fungals, cystic-fibrosis therapies, asthma therapies, emphysema therapies, respiratory distress syndrome therapies, chronic bronchitis therapies, chronic obstructive pulmonary disease therapies, organ-transplant rejection therapies, therapies for tuberculosis and other infections of the lung, fungal infection therapies, respiratory illness therapies associated with acquired immune deficiency syndrome, an oncology drug, an anti-emetic, an analgesic, and a cardiovascular agent.

A2 53. The aerosol composition of claim 51, wherein the nanoparticulate drug particles have an effective average particle size of less than about 400 nm.

54. The aerosol composition of claim 51, wherein the nanoparticulate drug particles have an effective average particle size of less than about 300 nm.

55. The aerosol composition of claim 51, wherein the nanoparticulate drug particles have an effective average particle size of less than about 250 nm.

56. The aerosol composition of claim 51, wherein the nanoparticulate drug particles have an effective average particle size of less than about 100 nm.

57. The aerosol composition of claim 51, wherein the nanoparticulate drug particles have an effective average particle size of less than about 50 nm.

58. The aerosol composition of claim 51, wherein the aerosol comprises a concentration of a drug in an amount of from about 0.05 mg/mL up to about 600 mg/mL.

59. The aerosol composition of claim 58, wherein the aerosol comprises a concentration of a drug selected from the group consisting of about 10 mg/mL or more, about 100 mg/mL or more, about 200 mg/mL or more, about 400 mg/mL or more, and about 600 mg/mL.

60. The aerosol composition of claim 51, wherein the droplets of the aerosol have a mass median aerodynamic diameter (MMAD) of about 2 to about 10 microns.

61. The aerosol composition of claim 60, wherein the droplets of the aerosol have a mass median aerodynamic diameter (MMAD) of from about 2 to about 6 microns.

62. The aerosol composition of claim 51, wherein the droplets of the aerosol have a mass median aerodynamic diameter (MMAD) of less than about 2 microns.

63. The aerosol composition of claim 51, wherein the droplets of the aerosol have a mass median aerodynamic diameter (MMAD) of about 5 to about 100 microns.

64. The aerosol composition of claim 63, wherein the droplets of the aerosol have a mass median aerodynamic diameter (MMAD) of about 30 to about 60 microns.

65. A method of making an aerosol of an aqueous dispersion of nanoparticulate drug particles, wherein said nanoparticulate drug particles comprise a poorly soluble drug, have an effective average particle size of less than about 1000 nm, and have a non-crosslinked surface modifier adsorbed on the surface thereof; wherein the method comprises:

- (a) providing an aqueous dispersion of said nanoparticulate drug particles; and
- (b) forming an aerosol comprising liquid droplets of said dispersion, wherein:
 - (i) essentially each droplet of the aerosol comprises at least one nanoparticulate poorly soluble drug particle and at least one surface modifier adsorbed to the surface of the drug particle, and

- (ii) the liquid droplets forming the aerosol have a mass mean aerodynamic diameter of less than about 100 microns.

66. The method of claim 65, wherein the drug is selected from the group consisting of proteins, peptides, bronchodilators, corticosteroids, elastase inhibitors, analgesics, anti-fungals, cystic-fibrosis therapies, asthma therapies, emphysema therapies, respiratory distress syndrome therapies, chronic bronchitis therapies, chronic obstructive pulmonary disease therapies, organ-transplant rejection therapies, therapies for tuberculosis and other infections of the lung, fungal infection therapies, respiratory illness therapies associated with acquired immune deficiency syndrome, an oncology drug, an anti-emetic, an analgesic, and a cardiovascular agent.

67. The method of claim 65, wherein the nanoparticulate drug particles have an effective average particle size of less than about 400 nm.

68. The method of claim 67, wherein the nanoparticulate drug particles have an effective average particle size of less than about 300 nm.

69. The method of claim 68, wherein the nanoparticulate drug particles have an effective average particle size of less than about 250 nm.

70. The method of claim 69, wherein the nanoparticulate drug particles have an effective average particle size of less than about 100 nm.

71. The method of claim 70, wherein the nanoparticulate drug particles have an effective average particle size of less than about 50 nm.

72. The method of claim 65, wherein the aerosol comprises a concentration of a drug in an amount of from about 0.05 mg/mL up to about 600 mg/mL.

73. The method of claim 72, wherein the aerosol comprises a concentration of a drug selected from the group consisting of about 10 mg/mL or more, about 100 mg/mL or more, about 200 mg/mL or more, about 400 mg/mL or more, and about 600 mg/mL.

74. The method of claim 65, wherein the droplets of the aerosol have a mass median aerodynamic diameter (MMAD) of about 2 to about 10 microns.

75. The method of claim 74, wherein the droplets of the aerosol have a mass median aerodynamic diameter (MMAD) of from about 2 to about 6 microns.

76. The method of claim 65, wherein the droplets of the aerosol have a mass median aerodynamic diameter (MMAD) of less than about 2 microns.

77. The method of claim 65, wherein the droplets of the aerosol have a mass median aerodynamic diameter (MMAD) of about 5 to about 100 microns.

78. The method of claim 77, wherein the droplets of the aerosol have a mass median aerodynamic diameter (MMAD) of about 30 to about 60 microns.

79. A method of administering the aerosol of claim 51 to a patient, wherein the aerosol comprises drug at a concentration of 10 mg/mL or greater, and wherein the patient delivery time for the aerosol administration is about 15 seconds or less.--

REMARKS

Applicants respectfully request formal examination of this application.

I. STATUS OF THE CLAIMS

Claims 1-50 have been cancelled, without prejudice or disclaimer thereof, and claims 51-79 have been added to the application. Applicants reserve the right to prosecute the subject matter of the cancelled claims in this or another application.